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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CR-18-00258-EJD JOINT STATUS MEMORANDUM

The parties in the above-captioned matter hereby file this joint status memorandum in advance of the hearing set for November 4, 2019. Statements from the government (Section I) and from the defense (Section II) are set forth below.

I. Government's Statement

A. The October 2, 2019 Hearing and Subsequent Developments

Defendants have filed a motion to compel production of documents from FDA and CMS. (Dkt. No. 67). The problem with Defendants' motion is that it seeks an order from the Court compelling the *prosecution* to produce the requested documents. Those documents, however, are in the possession,

custody, and control of FDA and CMS, and the prosecution does not have access to those materials. The defense contests that fact, but the record in this case proves the prosecution's lack of access, and there is no dispute that the prosecution's discovery obligations do not extend to documents to which the prosecution lacks access.[1]

In its briefing in response to Defendants' motion, and at subsequent hearings, the government has made clear that it has no objection to Defendants obtaining the documents they seek from the agencies. Indeed, the prosecution has done everything in its power to retrieve the requested materials on Defendants' behalf. Shortly after Defendants filed their motion, the government sent written requests to FDA and CMS asking for all of the document categories listed in Defendants' filing. The government then worked with the agencies to find solutions to challenges that would slow down or limit their production. On July 9, 2019, FDA sent a letter to all counsel in this case confirming its agreement to produce "all documents responsive to all six categories requested by the parties." (Dkt. No. 89-2). On July 12, 2019, CMS sent a letter memorializing its agreement to produce documents in its possession responsive to the government's requests. (Dkt. No. 89-3). From that date forward, the agencies have never withdrawn their agreements to produce responsive documents and, based on the prosecution's understanding of the facts, the agencies have worked diligently to follow through on those agreements. The defense complains that the agencies have not completed their productions, but

Leading up to the last hearing on October 2, 2019, the agencies made several productions of responsive documents consistent with their agreements to produce, and updated the parties regarding the status of their efforts. The defense raised several complaints regarding the approaches the agencies had taken to collect and produce documents. Following the hearing on October 2, 2019, the Court issued an Order requiring the parties to meet and confer with FDA and CMS regarding the issues Defendants had

[1] In a footnote below, the defense asks the Court to accept that the prosecution's agreement to produce discoverable materials held by FDA-CI Special Agent Scavdis means that the prosecution must have full access to the files of all FDA employees. This simply does not follow. The prosecution has never disputed that Special Agent Scavdis is a member of the investigative team, and that the prosecution is therefore able to ensure that any discoverable documents in his possession are produced. Indeed, the prosecution has been producing such documents and will continue to do so as required by its discovery obligations. But Scavdis's work as a special agent in this case does not prove the government's access to all of FDA's millions of regulatory records any more than the presence of U.S. Postal Inspection Service agents on the team confers access to every piece of paper maintained by the Postal Service.

raised regarding the agencies' document productions. (Dkt. No. 134). The Order also required the agencies to complete their document productions by October 25, 2019. (*Id.*).

On October 23, 2019, the parties participated in a telephonic meet-and-confer discussion including counsel representing FDA and CMS. That two-and-a-half-hour call—along with ongoing email correspondence between the parties—has afforded defense counsel opportunities to raise their specific questions with the agencies and gain useful information regarding the agencies' approach to document collection, review and production. The government offers the following update based on information learned from the agencies during those discussions.

B. The Agencies' Good-Faith Efforts to Address Defendants' Remaining Objections and the Current Status of Their Productions

1. CMS

The government understands that CMS has completed the first phase of its production and is currently working as quickly as possible to capture and produce any remaining documents from the time period recently expanded based on Defendants' requests.

In advance of the October 2, 2019 hearing, Defendants raised complaints regarding CMS's use of a date restriction (September 1, 2013 through December 31, 2016) in collecting and producing documents in response to the government's request. This objection understandably took CMS by surprise for several reasons. First, CMS had determined that its selected date range would capture the bulk of documents responsive to the six requests, and that its previous collection efforts would have captured any relevant documents from an earlier time period. Second, Balwani's counsel had proposed that very date range for CMS's document production in response to Balwani's subpoena in the SEC civil case. Third, CMS's July 12, 2019 letter had expressly indicated its intention to use that date range in collecting documents to respond to the government's request, and the Court had quoted that portion of CMS's letter in acknowledging the agency's agreement to produce responsive documents. In other words, CMS believed in good faith that its use of that date restriction was in compliance with the Court's order.

Following the October 2, 2019 hearing, CMS reviewed the Court's latest Order and the transcript from the hearing and came to understand that the Court wanted the agency to collect and produce

documents beyond its originally selected date range. In response, CMS immediately started that process, going back to its selected custodians and using search terms to collect documents going back to 2010 as requested by Defendants. Once that step was complete, CMS sent the collected documents to DOJ's Litigation Technology Service Center ("LTSC") so that LTSC could load those documents onto a database for CMS's review. That process is now complete and the documents are being prepared for review. Once CMS has access to the collected documents again on or about November 4, 2019, it will review the documents for responsiveness, privilege, and any other non-discoverable information, and select appropriate documents for production to the parties in this case. CMS estimates that this review will take approximately ten business days. LTSC will then process the document production—a final step that will take an estimated two weeks given LTSC's bandwidth. CMS will produce discoverable documents from this recently collected set as soon as possible. As discussed above, the timing of this production is driven primarily by factors outside CMS's control.

In connection with the expected additional production from CMS, it is important to note that the recent collection was relatively small, consisting of fewer than 900 documents after internal deduplication. CMS does not have the ability to deduplicate its upcoming production against the materials that it collected in response to the government's original request in 2017—materials that the government produced to the defense long ago. That means that this expected production may consist largely of documents that Defendants already have. CMS has indicated that it is willing to take on this potentially duplicative effort in order to accommodate the parties' requests and to avoid further dispute.

After reviewing CMS's recent productions, defense counsel identified a single CMS custodian who appeared not to be included in the agency's 2019 productions. Counsel for CMS explained to the defense that this custodian had only minimal involvement with Theranos early in the process, and that all of that custodians responsive documents had already been collected and provided to the prosecution in 2017. Following the October 23 call, CMS informed the parties that it had confirmed that the identified custodian's responsive documents had been collected and produced previously.

In response to additional questions from defense counsel, CMS also provided information regarding its data preservation practices with respect to current and former employees, confirming that those practices would have preserved relevant information in this case. CMS counsel also agreed to

confirm that non-electronic documents had been retrieved and produced, and subsequently confirmed for the parties that the majority of such documents would have been collected and produced to the prosecution in 2017. CMS is following up to locate and produce any additional responsive hardcopy files as soon as possible.

The prosecution is informed that the civil DOJ lawyer representing CMS plans to be present at the November 4, 2019 hearing, and that CMS in-house counsel will be standing by and willing to appear by phone should the Court wish to contact them for additional information.

2. FDA

FDA has completed the production of the documents it initially collected in response to the Court's July 19, 2019 Order. In addition, FDA has been responsive to Defendants' recently raised concerns, expanding its collection to include additional custodians identified by the defense. The review and production of materials from those custodians will be completed as soon as possible, but it will take approximately another month to load them onto the agency's review platform.

As explained in FDA's previous updates to the parties, the agency encountered technical issues in processing some of its materials that delayed production of a small subset of documents. Notwithstanding Defendants' speculation that these problems might be evidence of deleted files, FDA has said no such thing to the prosecution. FDA has been working on these technical issues and has resolved them to the extent possible. On the October 23 call, the agency provided an update regarding its continuing efforts to address technical issues as to one or two discrete categories of collected documents. Many documents previously subject to technical issues were produced on October 25.

The FDA's October 25 production also included at least one Spanish-language document that took the agency longer to review. Additionally, although the agency previously held off on reviewing documents from its Office of Chief Counsel, it has since reviewed those materials, and responsive, non-privileged documents were transmitted to the parties as part of the October 25 production.

After the October 2 hearing, the prosecution and the agencies sent multiple requests to defense counsel asking for specific information as to which custodians Defendants believed were improperly left out of the FDA's recent production. Eventually, on October 11, 2019, Defendants identified a handful of FDA document custodians who appeared not to have been included in the agency's 2019 collection

and productions. The FDA has reviewed that list of custodians and determined, based on their roles with respect to Theranos and overlap with other selected custodians, that it was reasonable not to include them in the initial round of collection. Although the agency stands by its original approach to document collection, it has informed the parties that it is expanding its collection efforts to include each of the custodians recently identified by the defense. To the extent those custodians are current FDA employees, the agency has already contacted them to initiate document collection. As to any former custodians on the list, FDA's information management staff estimate that it will take approximately four weeks to retrieve their documents.

Based on its knowledge of these custodians' roles, FDA anticipates that the number of unique and responsive documents collected from recently identified custodians will be relatively small. Like CMS, FDA cannot deduplicate its production against what it provided to the government in 2017, so it is likely that the defense already has many of the outstanding documents. FDA will, however, deduplicate the documents it is collecting now against its 2019 productions in order to accelerate its production. As these documents are compiled, FDA will load, review, and produce any responsive and discoverable materials as quickly as possible.

On the October 23 call, FDA provided responses to questions from the Defendants regarding document preservation for employees who have left the agency, the collection of non-electronic documents, and the time periods covered by FDA's collection efforts. FDA's answers on these topics gave no indication that relevant evidence had been lost or ignored.

Defendants have taken issue with redactions in FDA's production, alleging that the agency improperly withheld information necessary to understand the context of responsive communications. The prosecution and the agencies have requested that the defense provide examples of the purported overbroad redactions so that agency counsel can review them. Prior to the October 23, 2019 call, defense counsel sent a small number of example documents. FDA counsel has reviewed those specific documents and examined the unredacted versions to confirm for the parties that the redacted information is unambiguously nonresponsive, i.e., that it has nothing to do with Theranos. FDA has recently confirmed for the parties that it waived its deliberative process privilege as to Theranos, and did not redact or withhold Theranos-related documents on that basis. According to FDA counsel, its practice of

redacting such nonresponsive information sped up its production by allowing it to bypass the more granular review for privilege and third-party confidential commercial information. Contrary to Defendants' claims, the agency did not state that it used this method to avoid a careful *responsiveness* review. Nor did the agencies withhold information based on their views concerning what issues are relevant in this case. To date, the defense has not identified any documents where responsive information—or indeed any information about Theranos itself—was redacted. Regarding FDA's withholding of duplicate documents attached to emails in its production, the agency reports that it is currently evaluating its position on the issue after receiving from the defense a list of produced documents affected by this issue.

Finally, Defendants have objected to the absence of certain search terms in FDA's document collection protocols. The government agrees with the agencies that these complaints are unfounded. For example, Defendants contend that the terms "LDT" (an abbreviation for "laboratory developed test") and "waiver" should have been included as independent search terms in FDA's collection. In other words, Defendants' position is that the Court's Order entitles them to FDA documents that discuss the concepts of LDTs and waivers even if those discussions are not in the context of Theranos specifically and make no mention of the company. Defendants' relevance arguments aside, those documents simply are not covered by any of the six categories selected in Defendants' motion, the government's document requests, and the Court's Order. In fact, Balwani tacitly acknowledged as much in the SEC civil case; his subpoena to FDA included several document requests beyond the six at issue here, and that list of additional requests included at least one explicitly targeting information about LDTs. FDA should not be blamed for Defendants' failure to include that topic in the list of categories they selected in the criminal case.

The prosecution is informed that the civil DOJ lawyer representing FDA plans to be present at the November 4, 2019 hearing, and that FDA in-house counsel will be standing by and willing to appear by phone should the Court wish to contact them for additional information.

II. Defendants' Statement on FDA/CMS Productions

The Court has now twice ordered the FDA and CMS to complete their productions of all documents responsive to the defense's requests by a date certain. Most recently, on October 2, 2019,

after the agencies failed to meet the initial deadline set by the Court, the Court again ordered that production be completed "no later than October 25, 2019." ECF No. 134. October 25 has come and gone, and the agencies' productions are far from complete. In addition to the continued delays, the agencies are (1) unable to confirm that all responsive documents have been preserved, searched for, collected, and will be produced, (2) incapable of providing credible estimates of when their productions will be complete, and (3) in the case of FDA, are producing thousands of redacted documents and blank pages labeled "intentionally withheld." Notwithstanding the Court's clear directives on the matter, significant questions and uncertainties remain regarding when or if the defense will receive many of the important agency documents it has been seeking.

The defense filed its motion to compel production of these materials on April 15, 2019. ECF No. 67. The Court held a hearing on the motion on June 28, 2019, after which the Court entered an Interim Order that the "FDA and CMS shall provide the parties with specific information regarding the documents they agree to produce or object to producing." ECF No. 84. On July 19, 2019, following a second hearing on the defense's motion, the Court ordered the FDA and CMS to "search for and produce to the Prosecution all documents responsive to the six categories of documents" in Defendants' motion. ECF No. 111. The Court further ordered the FDA and CMS to complete their productions no later than October 2, 2019. *Id.* The agencies failed to do so. The parties appeared before the Court for a third hearing on the same motion, after which the Court again ordered the FDA and CMS to complete their productions, this time by October 25. ECF No. 134. At the hearing, the prosecution represented to the Court and the parties that the agencies were "on track to complete their productions of responsive documents either today or in the very near future."[2] That has not happened.

Pursuant to the Court's October 2, 2019 Order, the defense met and conferred with the FDA, CMS, and the prosecution over the last several weeks regarding Defendants' concerns with the agencies' productions. A civil Assistant United States Attorney from the same office as the prosecution, and who has been intimately involved in the agencies' production efforts, participated extensively in these conversations. The defense sought a response to the same question it has been asking for months: would

[2] Transcript of Proceedings Before the Honorable Edward J. Davila (October 2, 2019), at 4:12-14.

the FDA and CMS produce *all* documents responsive to the motion, and when? The answers from both the prosecution and the agencies revealed why they have been so reluctant to provide a direct response to a simple question: a troubling lack of diligence in ensuring that all responsive documents have been preserved, searched for, collected, and will ultimately be timely produced.

During the October 23, 2019 meet and confer between the prosecution, the civil AUSA, agency counsel, and the defense, the defense learned for the first time of a number of glaring deficiencies in the agencies' preservation and collection efforts. The agencies also could not provide clear estimates of the timing of further productions, leaving the defense once again in the dark about if and when the agencies' productions will be completed. The prosecution's speculation that the defense *probably* already has the outstanding documents is not correct; actual analysis of the data shows that over 95% of the documents produced by the agencies since the Court Order are new, not duplicative of prior DOJ productions.

A. CMS's Deficiencies

1. CMS has not made inquiries sufficient to assure the defense that all relevant documents and data for the full time period had been preserved.

2. CMS could not confirm that it had collected and produced all responsive non-email, hard-copy documents.

3. CMS could not provide a firm date by which the defense would receive documents from the 2010-2013 time period.[3] The status of any additional non-email or hard-copy document production from CMS is even hazier, as CMS would have only started collecting such documents days ago, at best.

B. The FDA's Deficiencies

1. The FDA could not confirm that it had preserved, collected, and produced all hard-copy documents for former employees, including employees who left the FDA *after* the prosecution issued a litigation hold in June 2017. This latter group of employees includes the primary FDA official with whom Theranos interacted.

[3] The government's statement claims that CMS was surprised by Defendants' objections to CMS's date restriction of September 1, 2013 through December 31, 2016. But Defendants' motion to compel—filed on April 15, 2019—specifically noted that "a CMS representative visited Theranos and toured its facilities in 2012" and that the "CDPH conducted an initial survey of Theranos in January 2012." ECF No. 67 at 4.

2. With respect to current employees, the defense learned that the FDA has instructed individual employees to manually search for responsive documents, including email, rather than perform a forensic collection, search, and review. The FDA's approach is unreliable and inconsistent with standard document collection practices. *See Nat'l Day Laborer Organizing Network v. USCIS*, Case No. 10-cv-3488 (S.D.N.Y. Jul. 13, 2012) (finding that "most custodians cannot be 'trusted' to run effective searches" and a "court cannot simply trust the defendant agencies' unsupported assertions that their lay custodians have designed and conducted a reasonable search").

3. The FDA could not provide an estimate as to when documents from additional, missing custodians would be produced, noting only that it would take at least *four weeks* just to locate and process the documents.

4. The FDA has taken other steps at a technical level that have deprived the defense of highly relevant—and exculpatory—evidence.[4] It appears that the FDA's approach to compliance with the Court's order is to look for ways to produce the narrowest possible set of documents. This includes not using "Theranos" as a standalone search term. The FDA also excluded key search terms necessary to fully comply with the Court's Order. For example, the FDA failed to include "Laboratory Developed Test" or "LDT" as search terms. They did not even search for "Theranos and LDT," among other crucial combinations. This is astonishing given how central the FDA's policies around the regulation of LDTs is to this case. Notwithstanding the prosecution's advocacy on behalf the agencies that these terms need not be searched, the agencies could not possibly produce all documents responsive to the Court's Order, especially categories 2 and 4, without these searches. The failure to deploy such central search terms likely explains the dearth of FDA documents created in 2014, Exhibit B (FDA Histogram), when the agency was heavily involved with making decisions about how and whether to regulate LDTs.

A. The FDA has either "intentionally withheld" or redacted at least 45% of its total production since the Court Order. Exhibit C (Pie Chart). Specifically, more than 4,586 documents that the FDA has produced pursuant to the Court's Order are blank pages marked as "Intentionally Withheld," including attachments to emails that are clearly responsive to the Court's Order. *See, e.g.*,

[4] Many of these deficiencies are set forth in an October 30, 2019 letter from FDA counsel. Exhibit A.

Exhibit D. The FDA claims that these documents are "duplicates" but they are not—e.g., the same document attached to three different emails with different recipients needs to be produced three times for each of the emails to have evidentiary use and significance. The FDA's approach has limited the evidentiary use of the documents and provided the defense with no ability to accurately locate these documents or establish as an evidentiary matter which witnesses had possession and knowledge of copies of the documents. Fundamentally, the FDA's stated position is not a proper basis to withhold highly relevant evidence.

B. Many of the documents that have been produced are also unintelligible due to the FDA's improper redactions for issues such as "non-responsiveness," "law enforcement," or "deliberative process." Exhibit E. These redactions are contrary to the prosecutions' and agencies' prior representations that the "FDA is not withholding responsive documents based on a determination of relevance" or "withholding documents … on the basis of deliberative process privilege." Dkt. 89-2 (FDA July 9, 2019 Letter); Dkt. 89 (July 15, 2019 Joint Status Memo). The FDA has stated that the documents it withheld under claims of deliberative process are unrelated to Theranos, but it is clear from the productions that the agency takes an extremely narrow view of that concept such that it is withholding, for example, key policy discussions that directly implicate regulation of Theranos's lab testing. The FDA even now admits that its "non-responsive" redactions are a catchall used to save time and avoid a careful review of the document for responsiveness. Exhibit A at 4.

C. The FDA was unable to explain the "technical issues" that led to hundreds of documents being withheld up until this point from the files of the primary FDA official with whom Theranos interacted. It appears that the term "technical issues" may be a euphemism for deleted files that the FDA is attempting to recover. *See* Exhibit A at 2 ("Approximately 1,114 partially-visible emails from custodian Alberto Gutierrez – there is no way to correct these email files. Accordingly, FDA is working to identify whether it has full versions of the emails from other custodians; to the extent it does not, it will produce the partially-visible emails.").

The information communicated by the agencies raises serious concerns about their efforts to comply with the Court's Orders to produce all documents responsive to the defense's requests, as well as the impact that the agencies' actions may have on the trial schedule. But it also throws into sharp

relief the pressing and continued need for a Rule 16 Order to hold the prosecution directly accountable for the agencies' productions.[5] The defense has consistently raised issues related to document preservation and collection. Yet it appears that the prosecution never bothered to inform the agencies that all documents responsive to the defense's requests should be preserved, collected, searched for, and produced. It is difficult to imagine that the prosecution would have done the same had it been subject to a Rule 16 Order. The defense has provided the government with examples of Brady material within recent productions that demonstrate far closer scrutiny of agency files is needed than has been demonstrated by FDA and CMS to date. The government must finally accept that it is not "off the hook for any Rule 16 obligation."[6] It is clear from the events to date that only the government would have the vested interest necessary to ensure compliance with the Court's Order to avoid the grave risk that Rule 16 and *Brady* material will go unpreserved and unproduced.

/ /

[5] The government again repeats its mantra that it lacks access to the agency documents. This is incorrect. Among other things, the record shows that the government's own agent had carte blanche access to FDA materials, even post-indictment. Notably, in the October 23, 2019 meet and confer call, the prosecution conceded that it currently has access to FDA files when it wants to control the production. In response to a defense request about email and other files of FDA-CI Special Agent Scavdis, the prosecution advised that it, and not FDA, would review and produce discoverable material, even where such documents are subject to the Order. The government makes an inapt analogy to the postal service in a footnote above, but the fact remains that the FDA agent had unfettered access to FDA files shattering the fiction that the government is a mere bystander here.

[6] Transcript of Proceedings Before the Honorable Edward J. Davila (October 2, 2019), at 17:8-9; *see also* Transcript of Proceedings Before the Honorable Edward J. Davila (July 16, 2019), at 40:6-17.

III. Proposed Pre-Trial Schedule

Consistent with the Court's order at the October 2, 2019 hearing, the parties jointly propose the pretrial schedule attached as Exhibit F be entered in this matter.

DATED: October 31, 2019

Respectfully submitted,

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Acting Under Authority Conferred
By 28 U.S.C. § 515

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